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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569,847	04/10/2006	Jac Yong Han	50413/013001	2565
21559	7590	08/30/2007		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER SAJJADI, FEREDOUN GHOTB	
			ART UNIT 1633	PAPER NUMBER
			MAIL DATE 08/30/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/569,847	Applicant(s) HAN ET AL.	
	Examiner Fereydoun G. Sajjadi	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 16-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/7/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to papers filed July 2, 2007. Applicant's response to restriction requirement of April 9, 2007 has been entered. No claims were cancelled, amended or newly added. Currently, claims 1-19 are pending in the application.

Election/Restrictions

Applicant's election without traverse of Group I, (claims 1-15), drawn to a method for long-term culture of avian spermatogonial stem cells, is acknowledged. Applicants' species election of "gonadal stromal cell", "stem cell factor", "chicken" and "staining with $\alpha 6$ -integrin antibody", also without traverse, is further acknowledged. Accordingly, claims 16-19 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected subject matter, there being no allowable generic or linking claim.

Applicant timely responded to the restriction (election) requirement in the Paper filed July 2, 2007. As the election was made without traverse, the restriction requirement is deemed proper, maintained and made FINAL. Claims 1-15 are under current examination.

References Listed in Specification

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, applications, or other information submitted for consideration by the Office, and MPEP § 609.04(a), subsection I. states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Objections to the Specification/Abstract

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-10, 12, 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Baguisi et al. (U.S. Patent Publication No.: 2002/0162134 effective filing date: Feb. 16, 2001).

The claims are directed to a method for culture of chicken spermatogonial stem cells (SSCs). The instant specification states: "Spermatogonial cells of avians originate from primordial germ cells (PGCs) that ...finally differentiated into spermatogonia in testis." (lines 19-26, p. 1). The instant specification further teaches that like PGCs, SSCs stain purplish red with PAS staining, that makes it possible to discriminate chicken SSCs from Sertoli cells and other cells (lines 13-20, p. 35). Thus absent a clear distinction between PGCs and SSCs, PGCs are interpreted as spermatogonial stem cells.

Baguisi et al. teach isolated avian gonadal cells from the testes (Title and Abstract), and methods of isolating and culturing the same. Specifically teaching the harvest of the gonads from chick embryos between days 7-8 and their grouping by sex (corresponding to preparation of chicken testis), and their dispersion by standard trypsinization procedure and culture in tissue culture plates (paragraph [0035], p. 4; limitation of claims 1(b), 1(c) and 2). Further teaching: "The PGCs can either be co-cultured with gonadal stromal cells (limitation of claims 4-6) or separated prior to culture on plates at 37° C." (limitation of claim 12). "The PGCs were cultured in DMEM with high glucose content and supplemented with 10% FBS, 5% chicken serum and growth factors (basic Fibroblast Growth Factor, Insulin Growth Factor-1 and Stem Cell Factor at 10 ng/ml and murine Leukemia Inhibitory Factor at 10units /ml to maintain their germ cell state." (paragraph [0050], p. 6; limitation of claims 7-10). The terms insulin growth factor 1 and insulin-like growth factor 1 appear interchangeably in the prior art.

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Baguisi et al. state that chicken PGCs have a high glycogen content and thus are identifiable by periodic acid Schiff staining (paragraph [0050], pp. 5-6; limitation of claim 14). Therefore by teaching all the limitations of claims 1, 2, 4-10, 12, 13 and 14, Baguisi et al. anticipate the instant invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 11 and 15 are rejected under 35 U.S.C. §103(a) as being unpatentable over Baguisi et al. (U.S. Patent Publication No.: 2002/0162134 effective filing date: Feb. 16, 2001), in view of Shinohara et al. (U.S. Patent Publication No: 2006/0265774; effective filing date April 15, 2003).

Baguisi et al. describe isolated avian gonadal cells from the testes (Title and Abstract), and methods of isolating and culturing the same. While Baguisi et al. additionally describe the harvest of chick gonads from embryos and their dispersion by standard trypsinization procedure and culture in tissue culture plates (paragraph [0035], p. 4), they do not describe treating the tissue with a mixture of collagenase and trypsin, the inclusion of an antioxidant in the culture medium, or the identification of the stem cells by staining with $\alpha 6$ -integrin antibody.

Shinohara et al. describe a method for growing spermatogonial stem cells *in vitro* (Abstract), wherein the testis is totally digested with collagenase, trypsin and DNase (paragraph [0065], p. 6; limitation of claim 3), and the dissociated cells are cultured in medium containing fetal calf serum and 2-mercaptoethanol (an antioxidant; paragraph [0102], p. 9; limitation of

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claim 11). To confirm the properties of the cells cultured, flow cytometry was carried out using antibodies to various markers that included rat antihuman $\alpha 6$ -integrin (paragraph [0104], p. 9).

Thus, Shinohara et al. cure the deficiency in Baguisi et al. for tissue preparation using collagenase and trypsin, and culturing the stem cells in the presence of an antioxidant and their subsequent identification using $\alpha 6$ -integrin antibody.

Therefore, it would have been *prima facie* obvious for a person of ordinary skill in the art to combine the teachings of Baguisi et al. and Shinohara et al. (as both describe methods for the preparation and culture of sperm stem cells as instantly claimed), with a reasonable expectation of success, at the time of the instant invention. A person of skill in the art would be motivated to isolate sperm stem cells from an avian testis using a combination of collagenase and trypsin, because said combination would be more efficient than using trypsin alone. A person of skill in the art would be further motivated to culture sperm stem cells in the presence of 2-ME, because the inclusion of an antioxidant in the medium was known to stabilize the cultured cells. Finally, the inclusion of anti $\alpha 6$ -integrin antibody would serve as a confirmatory marker test for the isolated stem cells.

Conclusion

Claims 1-15 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fereydoun G. Sajjadi whose telephone number is (571) 272-3311. The examiner can normally be reached on 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fereydoun G. Sajjadi, Ph.D.
Examiner, A.U. 1633



/Joseph Woitach/
Joseph Woitach
SPE 1633